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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
FRAZIER, BARBARA S	

ART UNIT	PAPER NUMBER
1611	

NOTIFICATION DATE	DELIVERY MODE
04/08/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/583,135	WEILL ET AL.	
	Examiner	Art Unit	
	BARBARA FRAZIER	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 December 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8,10 and 11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8,10 and 11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/10/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claims 8, 10, and 11 are pending in this application.

2. Claims 8, 10, and 11 are examined.

Specification

3. The disclosure is objected to because of the following informalities: the Brief Description of the Drawings does not include a description of Figure 35 (see pages 5-11 of the specification).

Appropriate correction is required. New matter must be avoided.

Claim Rejections - 35 USC § 112

4. The rejection of claims 8, 10, and 11 under 35 U.S.C. 112, first paragraph, regarding scope of enablement, is withdrawn in view of Applicant's amendments to claims 8 and 11.

5. The rejection of claims 8, 10, and 11 under 35 U.S.C. 112, first paragraph, regarding written description, is withdrawn in view of Applicant's amendments to claims 8 and 11.

Claim Rejections - 35 USC § 103

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Applicant's arguments, see pages 5-7, filed 12/10/09, with respect to the rejection(s) of claim(s) 8, 10, and 11 under 35 U.S.C. 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Crapo et al (WO 02/060383), Brurok et al (Biochem. Biophys. Res. Comm., 254:768-772, 1999), and Towart et al (WO 97/049390) as delineated below.

8. Claims 8, 10, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crapo et al (WO 02/060383, cited by Applicants) in view of Brurok et al (Biochem. Biophys. Res. Comm., 254:768-772, 1999) and Towart et al (WO 97/049390, cited by Applicants).

The claimed invention is drawn to a method for increasing the cytostatic or cytotoxic effects on tumor cells, and decreasing the cytotoxic effect on normal leucocytes of an anticancer medicinal product comprising one or more platinum derivative selected among platinum derivatives, wherein said method comprises administering to a patient treated with said anticancer medicinal product, an antitumoral and leukocyte-protecting amount of mangafodipir and wherein said platinum derivative is cisplatin or oxaliplatin (see claim 8). The amount of mangafodipir administered to said patient is from 1 to 100 mg/kg/day (claim 10). Also claimed is a composition comprising mangafodipir and cisplatin or oxaliplatin (claim 11).

Crapo et al teach a method of preventing or treating cancer using mimetics of superoxide dismutase (SOD) as the active agent or as a chemo- and/or radio protectant (abstract and page 7). Crapo et al teach various manganese-containing SOD mimetics which may be used as the SOD mimetic, including porphines and tetrapyrroles; manganese derivatives are preferred (pages 7 and 8). The compounds can be used in combination with other chemotherapeutic agents, such as bleomycin, **cisplatin**, adriamycin, and camptothicen; when used in combination therapy, the compounds can increase the anti-tumor effect of chemotherapy as well as prevent toxicity, in whole or in part, resulting from free radicals produced by agents such as bleomycin, **cisplatin**, and adriamycin (pages 8-9). Normal tissues which can be protected include leucocytes (page 9).

While Crapo et al teach the use of manganese-containing SOD mimetics, Crapo et al do not specifically teach that the manganese-containing SOD mimetic is mangafodipir (MnDPDP).

Brurok et al teach that MnDPDP possesses SOD mimetic activities (e.g., see abstract and page 768), as evidenced by reduced spin adduct formation with EST/DMPO, and by maintained urate production (pages 770-771).

Towart et al teach that dipyridoxyl based chelating agents, particularly manganese containing compounds are particularly effective in reducing the toxicity of anti-tumor agents (pages 2 and 3); MnDPDP is more particularly preferred (page 7).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to substitute MnDPDP (mangafodipir) for one of the

manganese-containing SOD mimetics in the methods of Crapo et al; thus arriving at the claimed invention. One skilled in the art would be motivated to do so, with a reasonable expectation of success, because mangafodipir is also known to possess SOD-mimetic activity, as taught by Brurok et al, and has also been previously used to reduce the toxicity of an antitumor agent, as taught by Towart et al. Therefore, since mangafodipir is another manganese-containing SOD mimetic known to possess chemoprotective activity, it would be within the purview of the skilled artisan to substitute a compound of similar structure and activity (i.e., mangafodipir) for the compound of Crapo et al, with a reasonable expectation of success.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BARBARA FRAZIER whose telephone number is (571)270-3496. The examiner can normally be reached on Monday-Thursday 9am-4pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BSF

/Ashwin Mehta/
Primary Examiner, Technology Center 1600